



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2020-N-1816]

Lavipharm Laboratories, Inc., et al.; Withdrawal of Approval of Five Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of five abbreviated new drug applications (ANDAs) from multiple holders of those ANDAs. The basis for the withdrawal is that these ANDA holders have repeatedly failed to file required annual reports for those ANDAs and have failed to satisfy the requirement to have an approved risk evaluation and mitigation strategy (REMS).

DATES: Approval is withdrawn as of [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

FOR FURTHER INFORMATION CONTACT: Kimberly Lehrfeld, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6226, Silver Spring, MD 20993-0002, 301-796-3137, Kimberly.Lehrfeld@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: The holder of an approved application to market a new drug for human use is required to submit annual reports to FDA concerning its approved application in accordance with §§ 314.81 and 314.98 (21 CFR 314.81 and 314.98). Additionally, in accordance with section 505-1 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355-1), the Agency determined that a REMS is necessary for all the applicable listed drugs that the ANDAs in table 1 reference to ensure the benefits of the listed drugs outweigh the risks. In accordance with section 505-1(i) of the FD&C Act, an ANDA is required to have a REMS if the applicable listed drug has an approved REMS.

In the *Federal Register* of September 25, 2020 (85 FR 60474), FDA published a notice offering an opportunity for a hearing (NOOH) on a proposal to withdraw approval of these five ANDAs because the holders of these ANDAs had repeatedly failed to submit the required annual reports and have failed to receive approval of a REMS for their products. The holders of these ANDAs did not respond to the NOOH. Failure to file a written notice of participation and request for hearing as required by § 314.200 (21 CFR 314.200) constitutes a waiver of the opportunity for hearing by the holders of the ANDAs concerning the proposal to withdraw approval of their ANDAs and a waiver of any contentions concerning the legal status of the drug products. Therefore, FDA is withdrawing approval of the five applications listed in table 1 of this document.

Table 1.--ANDAs for Which Required Reports Have Not Been Submitted and a REMS Has Not Been Approved

Application No.	Drug	Applicant
ANDA 077051	Fentanyl transdermal system film, extended-release, 25 micrograms (mcg)/hour (hr), 50 mcg/hr, 75 mcg/hr, and 100 mcg/hr	Lavipharm Laboratories, Inc., 69 Princeton-Hightstown Rd., East Windsor, NJ 08520
ANDA 085217	Acetaminophen and Codeine Phosphate Tablet, 325 milligrams (mg)/30 mg	Everylife, 2021 15th Avenue West, Seattle, WA 98119
ANDA 085638	Acetaminophen, Aspirin, and Codeine Phosphate Capsule, 150 mg/180 mg/60 mg	Scherer Laboratories, Inc., 2301 Ohio Dr., Suite 234, Plano, TX 75093
ANDA 085639	Acetaminophen, Aspirin, and Codeine Phosphate Capsule, 150 mg/180 mg/30 mg	Do.
ANDA 085640	Acetaminophen, Aspirin, and Codeine Phosphate Capsule, 150 mg/180 mg/15 mg	Do.

FDA finds that the holders of the ANDAs listed in table 1 have repeatedly failed to submit reports required by §§ 314.81 and 314.98 and section 505(k) of the FD&C Act (21 U.S.C. 355). Furthermore, the holders of the ANDAs listed in table 1 have failed to receive approval of a REMS for their products in accordance with section 505-1 of the FD&C Act. In addition, under § 314.200, FDA finds that the holders of the ANDAs have waived their opportunity for a

hearing and any contentions concerning the legal status of the drug products. Therefore, based on these findings and pursuant to the authority under section 505(e) of the FD&C Act, approval of the ANDAs listed in table 1 and all amendments and supplements thereto is hereby withdrawn as of [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

Dated: April 5, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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